DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2014

Adhezion Biomedical, LLC
Ms. Caridad Smith
Director of Regulatory Affairs and Quality Assurance
One Meridian Boulevard, Suite 1B02
Wyomissing, Pennsylvania 19610

Re: K133963
Trade/Device Name: SURGISEAL Twist™ Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: August 13, 2014
Received: August 14, 2014

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133963

Device Name
SURGISEAL Twist™ Topical Skin Adhesive

Indications for Use *(Describe)*

SURGISEAL Topical Skin Adhesive is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations.

SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92 is below:

Submitter Information:	
Name	Adhezion Biomedical, LLC
Address	One Meridian Boulevard Suite 1B02 Wyomissing, PA 19610
Phone Number	(828) 572-4201
Fax Number	(828) 726-7117
Establishment Registration	3006385287
Name of contact person(s)	Caridad Smith – Director of Regulatory Affairs/Quality Assurance Tracy Lofgren – Regulatory Consultant
Date prepared	August 27, 2014
Name of Device:	
Trade or proprietary names	SURGISEAL Twist™ Topical Skin Adhesive
Common or usual name	Device, Tissue Adhesive for Topical Approximation
Classification name	Class II
Classification Panel	General and Plastic Surgery Devices
Regulation	Class II, under 21 CFR 878.4010
Product Code(s)	MPN
Legally Marketed device(s) to which equivalence is claimed	SURGISEAL Stylus Twist™ Topical Skin Adhesive (K130474)
Reason for 510(k) submission	Device Modification – Dimensional Specification Change to Tip
Device Description	SURGISEAL Twist Topical Skin Adhesives are sterile, professional liquid topical skin adhesives containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. Each applicator is comprised of a plastic ampoule container contained within an applicator sleeve with the applicator tip. This Twist applicator tray is contained in an outer Tyvek pouch. When SURGISEAL is applied to the skin, it polymerizes in minutes. *In vitro* studies have shown that SURGISEAL acts as a physical barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

Adhezion BIOMEDICAL

Indications for use	SURGISEAL Twist Topical Skin Adhesive is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations. SURGISEAL may be used in conjunction with, but not in place of, deep dermal sutures.
Technological Characteristics	The technological characteristics of SURGISEAL Stylus Twist and SURGISEAL Twist Topical Skin Adhesives are equivalent in performance. SURGISEAL Twist consists of a monomeric (2-octyl cyanoacrylate) liquid adhesive formulation packaged in a single-use applicator. The device is a low viscosity formulation to allow for varied layered applications of the adhesive to the intended area and allow for either a single thick, continuous layer or two thin layers of the adhesive to the wound area. The smaller tip dimensions of the SURGISEAL Twist applicator is the <u>only</u> difference between the subject and predicate devices.
Substantial Equivalence	<u>Biocompatibility:</u> The biocompatibility testing that was previously conducted to the currently marketed devices, SURGISEAL Stylus Twist (K130474) per the International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing". The existing testing is deemed supportive of the modified device. Based on the results from those studies, the subject device is considered to be non-toxic, non-irritating, non-sensitizing and biocompatible and no additional biocompatibility testing was necessary.
	<u>Performance Testing:</u> The performance testing of SURGISEAL Twist Topical Skin Adhesive modified product is identical to the currently marketed product; therefore the performance testing provided in the Premarket Notification K130474 is the same. Additional bench testing was performed to support the dimensional tip specification modification to the currently marketed product. Bench tests included: Flexibility, Linear and Surface Coverage, Wound Closure Strength and Force Expression. In all cases, the dimensional tip specification modification SURGISEAL Twist Topical Skin Adhesive met specifications and demonstrated equivalence to the currently marketed device.
	<u>Sterilization and Shelf-Life</u> The sterilization process of the dimensional tip specification modification

	device remains unchanged. All products within the SURGISEAL Twist Topical Skin Adhesive product family are sterilized in accordance with the order of operation of the assembly. First to be sterilized is the filled ampoule containing the adhesive, by gamma irradiation in accordance with ISO 11137-2:2006. Then the finished bulk applicator in the secondary packaging is sterilized by ethylene oxide in accordance with ISO 11135-1and 2:2008. The proposed dimensional tip specification modification of SURGISEAL Twist™ Topical Skin Adhesives does not impact the 24 month (2 year) expiration date (shelf-life) of the currently marketing predicated devices.

Based on bench performance testing, the specification modification of the device, SURGISEAL Twist has demonstrated to be substantially equivalent to its currently marketed device from a safety and performance perspective, and has demonstrated that a dimensional tip modification to the product maintains approximation of wound edges.